IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IAN WALLACE, Plaintiff, vs. PHARMA MEDICA RESEARCH, INC.; TRIS PHARMA, INC.; ROXANE LABORATORIES, INC.; HIKMA LABS, INC.; and WEST-WARD COLUMBUS, INC., Defendants.	)	Cause No. 4:18-cv-01859-PLC

PLAINTIFF'S RESPONSE TO
TRIS PHARMA, INC.'S STATEMENT OF UNDISPUTED FACTS

COMES NOW, Plaintiff Ian Wallace, for the following responses to Defendant Tris Pharma, Inc.'s Statement without waiving his procedural objections set forth in the body of his response.

1. On December 9, 2019 Plaintiff, Ian Wallace, filed his Second Amended Complaint against Hikma Labs, Inc., Pharma Medica Research, Inc. ("Pharma"), Tris and others for injuries he allegedly sustained in contracting Hepatitis C during a blood drawing process at Pharma's St. Charles facility while participating in a medical study. See Second Amended Compliant, attached hereto as Exhibit A.

RESPONSE: Admits.

2. There were two medical studies which were designed to test a new medications. One of the medical studies was to test new medication designed, manufactured, supplied and created by Tris. See Exhibit A ¶ 12.

RESPONSE: Admits.

3. Defendant Pharma operated a screening clinic and Phase 1 clinic in St. Charles,

Missouri. See Exhibit A ¶ 2.

RESPONSE: Admits.

4. Pharma conducted studies of medications designed by others and included testson human volunteers. See Exhibit A ¶ 12.

RESPONSE: Admits.

5. These tests included health studies including blood draws. See Exhibit A ¶ 12.

RESPONSE: Admits.

6. Defendant Tris contracted with Pharma to conduct a study of a certain medication provided by Tris. See Exhibit A

RESPONSE: Admits.

7. Plaintiff was a voluntary participant in the study. See Exhibit A ¶ 3.

RESPONSE: Admits.

8. Tris contracted with Pharma, where Pharma and Tris specifically agreed that Pharma was not an agent of Tris.

RESPONSE: Plaintiff objects to Defendant's attempt to apply contract terms in a contract to which Plaintiff was not a party. Such contract terms are absolutely not binding upon Plaintiff. *See Texas Pacific Ry. Co v. Watson*, 190 U.S 287 (1903).

11. Independent Contractor Status

11.1 It is understood and agreed that CRO is an independent contractor and will not have any right to any of Tris benefits, not for any purposes be deemed or intended to be an employee of Tris. CRO agrees to make any payments or withdrawing required by the Internal Revenue Code of 1986, as amended, the regulations promulgated thereunder, social security and any related statutes or regulations.

RESPONSE: Plaintiff objects to Defendant's par. 11.1 as it does not set forth a fact as

required by Rule 56 and/or Local Rule 4.01., is unsupported by any evidence and is vague regarding who "understood and agreed." To the extent Defendant is quoting from a contract to which Plaintiff was not a party, Plaintiff objects as stated above in response to par. 8, above.

11.2 It is further understood that CRO is not an agent of Tris and Tris is not an agent of CRO and neither party is authorized to bind the other party with respect to any third party. *See* Master Service Agreement attached hereto as Exhibit B.

RESPONSE: Plaintiff objects to Defendant's par. 11.2 as it does not set forth a fact as required by Rule 56 and/or Local Rule 4.01. To the extent Defendant is quoting from a contract to which Plaintiff was not a party, Plaintiff objects as stated above in response to par. 8, above.

9. At all times relevant, Shabaz Kahn, M.D., was the vice president of clinical operations at Pharma. See Deposition of Shabaz Khan, M.D., attached hereto as Exhibit C.

RESPONSE: Admits.

10. Pharma was a contract research organization that did clinical trials for pharmaceutical companies. See Exhibit C, P. 6, L. 5-7.

RESPONSE: Admits.

11. Pharma's clinical location in St. Charles dealt with all clinical activities where Volunteer participants came and participated in a study. *See* Exhibit C, P. 14, L. 23-24; P. 15, L. 12-17.

RESPONSE: Admits.

12. Part of what Pharma did was take a brand name medication and conduct testing on the generic equivalent. See Exhibit C, P. 20, L. 5-9.

RESPONSE: Admits.

13. Pharma worked on a contract basis with pharmaceutical companies to test and gather data for testing pharmaceuticals that the pharmaceutical companies wanted to market. See Exhibit C, P. 19, L. 12-17.

RESPONSE: Admits.

14. Pharma conducted its studies pursuant to a protocol. See Exhibit C, P. 53, L. 6-8.

RESPONSE: Plaintiff objects to Defendant's statement as the cited testimony refers to the Roxane study, not the Tris study. The witness is Defendant's cited testimony described the protocol for "the study" which was deposition Exhibit 1, the Roxanne Study. (Ex. A p. 56). As such Plaintiff denies.

15. A scientific affair team and protocol writing team created the protocol for each study. See Exhibit C, P. 56, L. 5-9.

RESPONSE: Admits.

16. The sponsor did not have input in creating the guidelines for a study. See Exhibit C, P. 57, L. 3-6.

RESPONSE: Denies. The sponsor wrote, approved, and provided the guidelines. See Defendant's Ex. D p. 21, Plaintiff's Ex. B p. 21.

17. The guidelines required to be included in the protocol were determined by the FDA. See Exhibit C, P. 57, L. 6-7.

RESPONSE: Admits.

18. Pharma had a team of protocol writers who drafted protocols for each study. See Exhibit C, P. 61, L. 8-9.

RESPONSE: Admits.

19. The protocol writers were Pharma employees. See Exhibit C, P. 61, L. 19-20.

RESPONSE: Admits.

20. Pharma was required to draw blood from a needle stick rather than a catheter as the FDA did not approve a device that was used on a catheter called a mandarin or an obturator. Exhibit C, P. 81, L. 12-18.

RESPONSE: Denies. Defendant's same witness in the next question clarified catheters can be used but they cannot be left open. *See* Defendant's Exhibit C, p. 81; *see also* Plaintiff's Exhibit A, p. 81. He further testified on the immediately following pages catheters are allowed. *See* Defendant's Exhibit C, p. 83; *see also* Plaintiff's Exhibit A, p. 83. The witness that testified "scientific affairs [Pharma Medica Research, Inc. ("PMR")] and the sponsor" did not approve the catheters. *See* Defendant's Exhibit C, p. 84; *see also* Plaintiff's Exhibit A, p. 84. In fact, PMR used catheters in other studies. *See* Defendant's Exhibit D, p. 35; *see also* Plaintiff's Exhibit B, p. 81. A sponsor has to agree to use catheters. *See* Plaintiff's Exhibit A, p. 84.

21. The protocol governed how a particular study will be conducted. See Exhibit C, P. 102, L. 1-4.

RESPONSE: Plaintiff objects to the vague form of the statement, and the witness was referring to deposition Exhibit 1, the protocol for the Roxanne Study (Defendant's Exhibit C,

at p. 101-102). Plaintiff denies it is applicable to the Tris study at issue. Plaintiff admits it provided the protocol overall parameters.

22. Each study's protocol was prepared by a Pharma writing team which dictated a study's specific conduct. See Exhibit C, P. 103, L. 17-18.

RESPONSE: Denies. The protocol was written, approved and provided by the sponsor. (*See* Defendant's Ex. D p. 21).

23. Heather Jordan, M.D., worked as a principal investigator for Pharma from March 2015 until May 2019. See Exhibit D, Deposition of Heather Jordan, M.D., P. 12, L. 10-15; P 17, L. 20-21.

RESPONSE: Admits.

24. Dr. Jordan's duties included making sure each study to which she was assigned was conducted according to the protocol. See Exhibit D, P. 21, L. 19-21.

RESPONSE: Admits.

25. Protocol (or study guidelines) governed everything ranging from what medication to administer to the time a participant's blood was to be drawn and tested. See Exhibit D, P. 22, L. 9-13.

RESPONSE: Plaintiff admits the witness so testified but denying logically that any study guideline could control "everything." The guidelines were written, approved, and provided by the sponsor. See Defendant's Ex. D p. 21.

26. Protocol (or study guidelines) determined how the blood was to be drawn. See Exhibit D, P. 22, L. 14-17.

RESPONSE: Admits.

27. Protocol (or study guidelines) governed how the entire study was to be conducted. See Exhibit D, P. 23, L. 5-9.

RESPONSE: Admits.

II. Plaintiff's Listing of Additional Facts.

1. The study guidelines, also known as protocols, were provided, written, and approved by the sponsor according to PMR's Dr. Jordan. See Defendant's Ex. D p. 21; *See also*, Plaintiff's Exhibit B, p. 21. The sponsor's written protocol governs when blood is to be drawn, meal times, when doses are administered, time of blood draws, the use of a needle versus catheter, participant selection, and pre-screening testing. *Id.* at pp. 20-23. When using a catheter, the participant gets stuck only once. *Id.* at p. 38. For the studies at issue, a "hepatitis C" screening was not required for check-in because it was not specified in the study protocols. *Id.* at pp. 94-95. The protocol also determines if hepatitis C testing is performed at the conclusion of the study. *Id.* at pp. 96.

2. The study sponsors had the right to come in to conduct audits, monitor, and require insurance. *See* Plaintiff's Exhibit B, pp. 24, 28; *see also* Plaintiff's Exhibit A, p. 73.

3. Adverse event reports are sent to the sponsors. Plaintiff's hepatitis C adverse event report was sent to the sponsor, Tris Pharma, Inc. (hereinafter "Tris"), which then reported it to the federal government. *See* Plaintiff's Exhibit B at, pp. 75-76, 103.

4. PMR's witness, Dr. Kahn, testified that the study protocol "comes from what the sponsor wants, sponsor requirements, along with our scientific affairs team." *See* Plaintiff's Exhibit A, p. 53. Dr. Kahn also identified the Tris protocol. *Id.* at p. 52-53. Tris was a sponsor. *Id.* at p. 56-57.

5. Dr. Kahn agreed with the above-cited testimony of Dr. Jordan regarding what the protocols governed and further added that the sponsor's protocol also regulated criteria for admission to the studies, food and fluids, physical activity, criteria for removal, reporting adverse events, posture, and even the type of contraceptive devices that could be used by participants in the study. *Id.* at p. 63-73.

6. Tris, also had a "Master Agreement" in addition to its protocol that applied to PMR. (Ex. D par. 23), *See also*, Defendant's Ex. B, Doc. 116-2.

7. There was no obligation to report Plaintiff's extremely high liver enzyme levels unless it was required by the study protocol. *Id.* at p. 112. No one reported Plainitff's levls that steadily rose to 1,800 (normal is 10-40). Ex. A, at p. 105-114.

8. The study protocol in issue, which was authenticated at the depositions of Dr. Jordan (Plaintiff's Exhibit B p. 53-56), and Dr. Kahn (Plaintiff's Exhibit A, p. 52-53, *et seq*.) echo the testimony above. The protocol filed under seal as Plaintiff's Exhibit E. *See also*, Plaintiff's Ex. E, at par. 23.

Respectfully submitted,

WENDLER & ZINZILIETA, P.C.

By: /s/Brian M. Wendler
Brian M. Wendler, #39151 MO
Angie M. Zinzilieta, #69783 MO
900 Hillsboro Ave., Suite 10
Edwardsville, Illinois 62025
Phone: (618) 692-0011
Fax: (618) 692-0022
Email: wendlerlawpc@gmail.com
Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I, the undersigned, hereby certifies that a true and correct copy of the foregoing was filed with the Court's e-filing system and transmitted via electronic mail to the following parties of record on December 10 , 2020:

Ms. Terese A. Drew
HINSHAW & CULBERTSON, LLP
701 Market Street, Suite No. 1375
St. Louis, Missouri 63101-1843
Phone: (314) 241-2600
Fax: (314) 241-7428
Email: tdrew@hinshawlaw.com
Attorney for Pharma Medica and Tris Pharma

Mr. Brian K. McBrearty
LITCHFIELD CAVO, LLP
222 South Central Avenue, Suite No. 110
St. Louis, Missouri 63105
Phone: (314) 725-1227
Fax: (314) 724-3006
Email: mcbrearty@litchfieldcavo.com
Attorney for Roxane Laboratories, Inc., Tris Pharma, Inc., & West-Ward Columbus, Inc.

By: /s/Brian M. Wendler